

DEPARTMENT OF HEALTH AND HUMAN SERVICES

PUBLIC HEALTH SERVICE

**SUBSTANCE ABUSE AND MENTAL HEALTH  
SERVICES ADMINISTRATION**

CENTER FOR SUBSTANCE ABUSE TREATMENT  
CENTER FOR MENTAL HEALTH SERVICES  
CENTER FOR SUBSTANCE ABUSE PREVENTION

**COOPERATIVE AGREEMENT TO STUDY CHILDREN OF WOMEN WITH  
ALCOHOL, DRUG ABUSE AND MENTAL HEALTH (ADM) DISORDERS  
WHO HAVE HISTORIES OF VIOLENCE**

SHORT TITLE: CHILDREN'S SUBSET STUDY

**Guidance for Applicants (GFA) No. TI 00-006  
Part I - Programmatic Guidance**

Catalog of Federal Domestic Assistance (CFDA) No. 93.230

Under the authority of Section 501(d)(5) of the Public Health Service Act, as amended (42 USC 290aa), and subject to the availability of funds, the SAMHSA Center for Substance Abuse Treatment will accept applications in response to this Guidance for Applicants for the receipt date of June 13, 2000.

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## Part I - PROGRAMMATIC GUIDANCE

### Table of Contents

[Note to Applicants: In order to prepare an application, PART II, A General Policies and Procedures Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements® (February 1999 edition), must be used in conjunction with this document, PART I, A Programmatic Guidance.®]

Section I - <b>Overview</b> .....	1
Purpose.....	1
Eligibility.....	1
Availability of Funds.....	2
Period of Support.....	2
Section II - <b>Program Description</b> .....	2
Supporting Documentation.....	2
Target Population.....	3
Program Plan.....	3
Goal.....	3
Cooperative Agreement- Roles.....	4
Design.....	7
Methodology and Evaluation.....	8
Measures/Parameters/Indicators.....	8
Section III - <b>Project Requirements</b> .....	9
A. Project Description.....	9
Statement of the Problem.....	9
Target Population.....	10
Purpose and Goals.....	10
B. Project Plan.....	11
Design.....	11
Methodology and Evaluation.....	12
Measures/Parameters/Indicators .....	12
Data Collection, Fidelity and Analyses.....	13
C. Project Management.....	14
Implementation Plan.....	14
Organization.....	14
Staff.....	15
Equipment/Facilities .....	15
Budget.....	15
Other Support.....	16

Post Award Requirements..... 16

Section IV - <b>Review of Applications</b> .....	16
Guidelines.....	16
Review Criteria.....	17
A. Project Description.....	17
Statement of the Problem.....	17
Target Population.....	18
Purpose and Goals.....	18
B. Project Plan.....	19
Design.....	19
Methodology and Evaluation.....	20
Measures/Parameters/Indicators .....	20
Data Collection, Fidelity and Analyses.....	21
C. Project Management.....	22
Implementation Plan .....	22
Organization.....	22
Staff.....	23
Equipment/Facilities .....	23
Budget.....	24
Other Support.....	24
Section V - <b>Special Considerations/Requirements</b> .....	24
Population Inclusion Requirement.....	24
Government Performance Monitoring.....	24
Healthy People 2000.....	24
Consumer Bill of Rights .....	24
Promoting Nonuse of Tobacco.....	24
Supplantation of Existing Funds.....	24
Letter of Intent.....	24
Coordination with Other Federal/Non-Federal Programs.....	24
Single State Agency Coordination.....	24
Intergovernmental Review.....	25
Confidentiality/Human Subject Protection.....	25
Section VI - <b>Application Procedures</b> .....	25
Application Receipt and Review Schedule.....	25
Consequences of Late Submission.....	26
Application Requirements/Component Checklist.....	26
Terms and Conditions of Support.....	32
Award Decision Criteria.....	32
Contacts for Additional Information.....	33
Appendices	
A. Bibliography.....	34

B. Format for Description of Interventions.....	37
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## Section I - OVERVIEW

*The ACooperative Agreement to Study Children of Women with Alcohol, Drug Abuse, and Mental Health (ADM) Disorders who have Histories of Violence,@seeks to generate and apply empirical knowledge about the effectiveness of trauma-informed, culturally relevant, and age-specific intervention service models for this target population of children. The objective for the study is to identify models of care for the field that will prevent (or reduce) the intergenerational perpetuation of violence, substance abuse and mental health problems, and reduce the impact of violence in the lives of children whose mothers have co-occurring disorders and histories of trauma.*

### **Purpose**

The Substance Abuse and Mental Health Services Administration (SAMHSA) announces the availability of cooperative agreements to support a sub-study to the "Women, ADM Disorders and Violence II@Study. This program, hereinafter referred to as "Children's Subset Study,@solicits applications from Phase I grantees for cooperative agreements to conduct this Subset Study. It also solicits an application from the SAMHSA Women, Co-occurring Disorders and Violence Study Coordinating Center for additional funding in order to expand their scope of work for this Subset Study. Please do not address AWomen, ADM Disorders, and Violence Phase II@(TI 00-003) issues in your application for this GFA.

This study will evaluate children 5 to 10 years of age who have been impacted by their mother's co-occurring disorders and their mother's history of violence. A cross-site process and outcome evaluation of age-specific interventions and services will be conducted.

This Knowledge Development and Application (KDA) program is a result of a partnership among SAMHSA and its three Centers--the Center for Substance Abuse Treatment (CSAT), the Center for Substance Abuse Prevention (CSAP), and the Center for Mental Health Services (CMHS).

Due to the complexity of the Children's Subset Study, it will require substantial programmatic involvement of Federal staff from all three of the SAMHSA Centers. The cooperative agreement mechanism is being used because it allows the Federal Government and/or its representative contractors to provide technical assistance to sites, coordinate the development of evaluation designs, collect and analyze data, participate on the Steering Committee, and convene meetings.

### **Eligibility**

Applications for the Children's Subset Study may be submitted only by current SAMHSA Women, ADM Disorders and Violence Phase I study grantees who are also applying to the "Women, ADM Disorders and Violence II@Study. Only those receiving a Phase II award will be eligible to receive a

Children's Subset award. Phase I grantees have already: (1) established an integrated system of care for women with co-occurring disorders who have histories of physical and sexual abuse, (2) determined the most promising services intervention models for this population, and (3) developed project protocols in compliance with multi-site requirements established by the steering committee. The Children's Subset Study is the offspring of the parent study. During Phase I, the study grantees established a Children's subcommittee whose main purpose was to develop parameters for the Children's Subset Study. In Phase I, the Children's subcommittee: (1) developed study goals and objectives, (2) established the common service intervention, and (3) developed the multi-site protocol for the Children's Subset Study.

Only the current Coordinating Center for the SAMHSA Women, ADM Disorders and Violence Study is eligible to apply for funds to carry out additional tasks for the Children's Subset Study. The Coordinating Center is currently in the second year of its peer and National Advisory Council approved 5-year project period. The Coordinating Center is an integral part of the Women, ADM Disorders, and Violence Study. Therefore, it is critical that continuity of the study be maintained by its leadership role during the Phase II study and during the concurrent Children's Subset Study. Its continued responsibility for coordination, technical assistance, evaluation expertise, and advice to the overall Steering Committee's Children's Subcommittee established during Phase I are essential to guide those study sites selected to receive a Children's Subset Study award.

### **Availability of Funds**

It is estimated that \$1.2 million will be available to support up to 5 awards for study sites and one award for the Coordinating Center in FY 2000. The amount of an award is estimated at no more than \$200,000 in total costs (direct + indirect ) per fiscal year for both the study sites and the Coordinating Center. Actual funding levels will depend upon the availability of appropriated funds.

Funds may be used by the study sites and the Coordinating Center to conduct all aspects of data collection and evaluation. A limit of 35 percent of the funds may be used to develop and enhance intervention services for children by site applicants.

### **Period of Support**

Support may be requested for a period of up to three (3) years. Annual awards will be made subject to continued availability of funds and progress achieved.

## **Section II - PROGRAM DESCRIPTION**

### **Supporting Documentation**

Knowledge gained from CSAT's and CSAP's programs for women and children about the impact of violence, and from the CMHS program exploring the role of physical and sexual abuse in the lives of

women with serious mental illness has raised concerns and questions about the complex interaction of trauma, substance abuse, and mental health disorders on women and their children.

Many of these women have children who have witnessed family violence or sexual abuse, and/or have been abused or neglected. These children may be experiencing immediate and latent consequences of such abuse that may include physical and/or psychological trauma. The severity of symptoms and the degree to which symptoms interfere with children's development are affected by a number of factors. Evidence suggests that abuse and neglect in early childhood may lead to aggressive behavior, alcohol and other drug abuse, poor physical health, and self-punishing behavior. These children are more likely than unexposed children to become batterers or victims themselves, and the emotional and developmental scars experienced by them may persist for a lifetime. A child's overall developmental level and available coping abilities will influence the type of intervention required to promote adaptive behavior, resilience, and promote social and emotional well-being. (Augustyn, et. al., 1995; and Widom, 1989).

### **Target Population**

The target population is children (age 5 to 10 years old) of the women in the Women, ADM Disorders and Violence II study. To be included in the study, the children must have in-person contact at least weekly with the study participant who is also their mother/caretaker.

### **Program Plan**

#### **Goal**

The primary goal of the Children's Subset Study is the generation of empirical knowledge about the effectiveness of trauma-informed, culturally relevant, and age-specific intervention service models for this target population of children. Considering that children may be affected by parental ADM disorders in conjunction with their mother's history of violence/trauma, and the multifaceted and long-term problems that may result, it appears that many still do not receive the services and support they need to help them with their problems (Finkelhor and Dzierba-Leatherman, 1994). It is likely that behavioral health problems of young children are not diagnosed due to misunderstanding on the part of practitioners and gatekeepers, inadequate assessment instruments, social stigma, and lack of access to appropriate, culturally competent, child-focused, age-appropriate interventions and services (Groves et al., 1993 and Zuckerman et al., 1995). SAMHSA seeks to answer the following question:

- # Do trauma-informed, age-specific interventions for children including concurrent services for mother and child as compared to children's services as usual yield: (1) increased self awareness, self worth, and self identity; (2) increased healthy relationships; (3) improved self care; and (4) improved safety?

The objective for the study is to identify models of care for the field that will prevent (or reduce) the intergenerational perpetuation of violence, substance abuse and mental health problems, and reduce the impact of violence in the lives of children whose mothers have co-occurring disorders and histories of trauma by: a) reducing risk factors related to potential substance abuse, mental health and trauma dysfunction, b) increasing resiliency factors and coping skills, and c) improving emotional and behavioral health.

### **Cooperative Agreement - Roles**

Steering Committee: The implementation of the Children's Subset Study will involve the cooperation and collaboration of: (1) the Study Sites, (2) Consumer/Survivor/ Recovering persons (C/S/Rs) from each of the Women, ADM Disorders, and Violence study sites, (3) the Coordinating Center, and (4) Federal staff. Representatives of these four groups will comprise the Steering Committee. The Steering Committee of the Women, ADM Disorders, and Violence program established major subcommittees in Phase I (including a Children's subcommittee) and may continue to establish new subcommittees and retire others as it strives to accomplish its objective in Phase II. The overall program requires all participants to understand their particular roles and to make adjustments in individual goals to achieve the overall success of the program.

The Steering Committee described here is the same Steering Committee for the main Women, ADM Disorder and Violence Phase II Study. It will be composed of the project director of the Coordinating Center, the project director from each of the study sites, and two additional site representatives (one of whom must be a C/S/R), and SAMHSA staff. The chair of the Steering Committee will be one of the grantees and will be appointed by the CSAT Director. SAMHSA staff will participate as full members of the subcommittees that are formed. The Steering Committee will continue with consensus agreement on most decisions. All decisions which cannot be made by consensus will be made by majority vote. In terms of voting on Steering Committee issues, the votes are tallied as: two votes per site (project director and C/S/R), two votes from SAMHSA, and one vote from the Coordinating Center. AEx Officio members may be elected jointly by SAMHSA staff, project directors and C/S/Rs. AEx Officio members may not vote. SAMHSA retains authority to override recommendations made by the Steering Committee that are inconsistent with the goals of the GFA.

The Children's subcommittee and the Women, ADM Disorders and Violence Steering Committee meet concurrently. The first meeting will be convened at the request of SAMHSA within one month of the awards. It is estimated that at least three meetings will be needed in each of the three years of the project. There may also be up to two additional meetings per year for the Children's subcommittee to carry out its tasks. Meetings will be held in the Washington D.C., area. Children's Subset Study applicants should budget (travel, lodging, and per diem) for two participants, the Children's Subset Study Evaluator and Clinician, per meeting. Due to the nature of the interwoven studies, these two additional persons are also required to attend the Women, ADM Disorders and Violence Steering Committee meetings.

All participating study sites must agree to abide by the common protocol study design and policy recommendations developed by the Children's Subcommittee and any required SAMHSA approvals set forth in the terms and conditions of the grant award.

The responsibilities of the Steering Committee subcommittees are set forth in broad terms on pages 29-31 of the March, 1998 GFA No. TI 98-004, Women and Violence, and remain as described.

Consistent with the provisions of 45 CFR 74.36, the Steering Committee will develop policies on data sharing and access to data and materials.

#### Coordinating Center:

For the Children's Subset Study, the Coordinating Center is primarily responsible for: (1) providing technical assistance to the study sites; (2) monitoring data collection procedures; (3) planning and providing logistical and technical support at meetings; (4) providing advice on common service intervention; (5) aiding in development and refinement of multi-site protocol; (6) identifying common instruments; (7) distributing multi-site protocol and instruments to the study sites; (8) analyzing data from the multi-site study; (9) producing and disseminating reports including knowledge products; and (10) conducting site visits. For a description of the full role of the Coordinating Center in the Women, Co-occurring Disorders, and Violence Study refer to pages 27-28 of the March, 1998 GFA No. TI 98-004.

Study Sites: Study Sites must participate in, and cooperate fully with, the Steering Committee, the Coordinating Center, and Federal staff in the implementation and evaluation of their projects. Activities include: (1) compliance with all aspects of the terms and conditions of the cooperative agreement; (2) provision of information necessary for SAMHSA to meet reporting requirements of the Government Performance and Results Act (GPRA); (3) cooperation with the Coordinating Center in accepting guidance and responding to requests for information relevant to the Program; and, (4) cooperation with Federal staff in accepting guidance and responding to requests for information relevant to the Program. In addition, each Children's Subset Study site evaluator and clinician must participate on the Women, ADM Disorders and Violence Steering Committee and the Children's subcommittee to: (1) refine multi-site questions, hypotheses, and the process and the outcome evaluation protocol; (2) use common interview protocols and other data collection instruments; (3) complete annual Administrative Reporting Form (ARF); (4) adhere to format, content, and timetable for submitting data to the Coordinating Center; (5) participate in annual site visits; (6) participate in interviewer training; and (7) participate in workgroups for developing 6 and 12 month follow-up interviews. Finally, study site grantees are expected to take advantage of the technical assistance that will be available from Federal staff and the Coordinating Center in post-award activities.

Because of the importance of understanding issues from a C/S/R perspective, it is required that each

study site participate fully in Steering Committee and Coordinating Center recommendations for implementing C/S/R involvement and participation. The basic principle to be followed is that fostering C/S/R integration in all aspects of the project is a crucial element to its success. Because the role of the site-elected C/S/R representative requires that they vote on Steering Committee decisions, the site is expected to provide them with the resources and technical assistance necessary to ensure their full understanding, participation, and fully informed representation.

Study sites and the Coordinating Center will submit annual non-competing continuation applications during Phase II. In addition, study sites will have regular reporting requirements to the Coordinating Center and SAMHSA. The content and timing of these regular reports will be developed by the Coordinating Center in consultation with the Steering Committee.

The sites are responsible for their own site-specific publications. Publications will be written and authorship decided using procedures developed by the Steering Committee. All participants will be subject to the publication/authorship policies to be developed by the Steering Committee. The quality of publications resulting from the Program will be the responsibility of the authors. (NOTE: Publications on which SAMHSA staff are included as authors or co-authors will receive internal agency clearance.)

Federal Staff: The cooperative agreement mechanism is only used when substantial post-award Federal programmatic participation in the conduct of the Program is required. It is anticipated that the SAMHSA participation in this program will be substantial. The government project officers (GPOs) will monitor the overall progress of the program. SAMHSA's role will be to:

- # Participate on the Steering Committee, program subcommittees, or other work groups established to facilitate accomplishment of the program goals.
- # Provide guidance on study design requirements.
- # Ensure accountability of study sites and Coordinating Center.
- # Arrange meetings designed to support activities of the individual cooperative agreement awardees.
- # Provide technical assistance in implementing program activities throughout the course of the program.
- # Review and approve each stage of program activities.
- # Conduct site visits to monitor the development and implementation of the programmatic activities and/or engage consultants to advise on programmatic issues and conduct site visits.
- # Provide support services or outside consultants for training, evaluation, and data collection.
- # Provide guidance to enhance the potential replicability of results.
- # Author or co-author publications to disseminate program findings.
- # Provide technical assistance on strategies to enhance the dissemination and application of study findings in States and localities.

## Design

This three year activity is conceived as a Subset Study of Phase II of the Women, ADM Disorders and Violence Study and will function concurrently. The site applicants must have programs currently offering prevention services and interventions for the children of clients who will be participating and receiving services under the larger study. Applicants for the Subset Study are expected to develop and implement service interventions that are culturally, developmentally, and age appropriate (5-10 years) to foster the children's emotional, social, and cognitive development. Due to the importance of understanding the issues from a consumer/ survivor/recovering person's perspective, it is expected that adult C/S/Rs whether they are mothers or not mothers, will be involved in planning and implementing the proposed intervention and study design at each study site.

Evaluation, including both the multi-site process and outcome protocols being developed by the Children's Subcommittee and Coordinating Center in Phase I, is the central component of this GFA. The design consists of a multi-model one-year service intervention study with quasi-experimental (non-random) comparison groups. Since the data will be pooled from each participating site, each site must utilize the same service intervention. A common interview protocol will be administered at baseline, six, and 12 months on the enrolled subjects. Two conditions will be compared in this design: (1) trauma-informed children's services, the experimental/intervention group; and (2) services as usual, the control/comparison group. Children for both groups must meet the same study eligibility criteria (as described under Target Population) and be age and gender comparable. (Note: Services as usual are expected to be less trauma-informed, less integrated, less comprehensive, and have a lower involvement of C/S/Rs than the trauma-informed services).

The following core interventions must be offered in the experimental/intervention group:

- # Assessment (Common)
- # Service Coordination and Advocacy: (Includes individualized family service planning in individual therapy, crisis intervention, childcare/daycare/learning center, family therapy, family trust building, multi-family group, psychiatric intervention, medication management, recreation, school, medical, social services, referral and follow-up).
- # Skills Building Group: (Relationship building including: group based, sharing, respect for others, empathy, taking turns, verbalization of feelings, play, anger management, expression of affect, communications, conflict resolution, language to discuss drug and alcohol abuse, mental illness and traumatic experiences, self-soothing, trust building, and clarifying responsibility in relationships).
- # Safety: Safety plan development and boundaries
- # Self-care
- # Identity

## **Methodology and Evaluation**

In Phase II of the multi-site study, grantees will examine services under two different groups; intervention group and comparison group. The children in the intervention group must be children of the mother/caregiver in the intervention group of the AWomen, ADM Disorders, and Violence II@study, whereas the children in the comparison group must be children of the mother/caregiver participating in the comparison group of the same study. Children in the two conditions will participate in the same screening and assessment, baseline interview, and follow-up procedures.

Outcome variables will be measured at the clinical/individual levels. Qualitative and quantitative measurements will be taken at the following intervals: 1) The qualitative process evaluation will be administered annually to capture the nature and scope of service delivery and care within the experimental framework and the process of care at the comparison site. 2) The quantitative outcome evaluation will occur at baseline, six months and 12 months after baseline for children in the two groups, regardless of whether they are still receiving services. (This timeline enables SAMHSA to meet the GPRA timeline requirement.) The protocol for the outcome evaluation of the Children's Subset Study is being developed by the Children's Subcommittee as promulgated by the Steering Committee during Phase I with significant input and technical advice from the Coordinating Center.

## **Measures/Parameters/Indicators**

The following children's outcomes must be addressed:

### Clinical/Individual Outcomes

- # Improved Relationships
  - # Shows respect for others.
  - # Increased ability to identify individual with whom the child has a trusting relationship (child chooses positive adult).
  - # Improved healthy relationships with peers.
  - # Increased (age appropriate) community connectedness.
  - # Increased ability to express emotions through language versus acting out or withdrawing.
  - # Increased awareness of effects of substance abuse, mental illness, and trauma on families and relationships.
- # Safety
  - # Formulation of a safety plan.
  - # Understanding it is not my fault and/or my family is not bad.
- # Self-care
  - # Increased ability to self-soothe, attend, and focus.

- # Improved knowledge of personal hygiene.
- # Verbalization of physical health indicators.
- # Identity
  - # Positive view of self.
  - # Increased self awareness, self worth, and self identity.
  - # Child involvement in articulating/identifying their needs.
  - # Increased sense of hope and control over future.
  - # Feels AI am not alone, not a victim.@

### **Section III - PROJECT REQUIREMENTS**

**Project Summary:** In 5 lines or fewer, 72 characters per line, applicants must provide a project summary for later use in publications, reporting to Congress, press releases, etc., should the application be funded. This may be the first 5 lines of the Project Abstract.

Site applicants and the Coordinating Center applicant must provide the information specified below under the proper section heading. The information requested relates to the individual review criteria in Section IV of the GFA.

#### **A. Project Description**

##### **Statement of the Problem**

##### ***Site applicants must:***

- # Describe the problems to be addressed by this study of children who have mothers with histories of violence and co-occurring disorders and the impact of these problems on the children.
- # Provide evidence of the ethnic and cultural variations found in the overall population as well as the proposed study sample.
- # Demonstrate the need for service models of care for the proposed sample.
- # Provide a literature review that demonstrates an understanding of the state-of-the-art and/or science related to children of women who have histories of violence and co-occurring disorders. The literature review must reflect the current state of knowledge regarding culturally competent services in this area and appropriate discussion that demonstrates how the reference citations relate to the design being proposed and the population to be served.

These data should be presented against a backdrop of the actual availability of children's services that addresses the identified needs of the target population. For this purpose, applicants must:

- # Provide descriptions of existing services.
- # Provide descriptions of enhanced services created/implemented as part of this program.

***Coordinating Center applicant must:***

- # Provide a literature review that demonstrates an understanding of the state-of-the-art and/or science related to the children of women who have histories of violence and co-occurring disorders.

**Target Population**

***Site applicants must:***

Describe the sample population in both the intervention and comparison groups. The distribution of identified services needs and associated demographic characteristics must be provided. Evidence documenting that these children are the children of women who are high end users must be provided. If exclusions of children of these high end users are planned on any basis other than those indicated in the definition of the target population, these must be explained and justified.

***Coordinating Center applicant must:***

- # Demonstrate an understanding of the definition and needs of the target population.

**Purpose and Goals**

***Site applicants must:***

- # Describe how the proposed project purpose addresses the various dimensions of the problem as stated and is based upon available evidence regarding what might be accomplished.
- # Provide an annotated outline of key steps and projected time-line for each goal and objective.
- # Describe how the goals, objectives, and time-tables reflect realistic strategic development in the context of current level of service and intervention development.
- # Describe how the proposed project goal(s) will support the generation of both qualitative and quantitative information and data that are: (a) based on prior evidence and innovation; (b) feasible in terms of issues that are addressed; (c) reflective of C/S/R involvement; and (d) capable of generating appropriate evaluation data.
- # Describe the potential contributions to the field, including new interventions (e.g., services approaches, treatment progress measures, feasibility of integrated services, and policy change).

***Coordinating Center applicant must:***

- # Demonstrate an understanding of the program goals and objectives.
- # Describe how technical assistance will be provided to the study sites so that they can accomplish their goals and objectives.
- # Describe plan for providing logistical and technical support at meetings.

**B. Project Plan**

**Design**

***Site applicants must:***

- # Describe how the site will implement the standardized cross-site service intervention.
- # Provide a description of the Trauma-Informed Children's Services and the Services as Usual at their site(s) by following the Format for Description of Interventions outline in Appendix B.
- # Provide a description for both the intervention and comparison group that includes: recruitment strategies, points of entry, eligibility for services, service array, service providers, treatment duration, organizational and staffing plans, level and type of C/S/R involvement, and specific clinical interventions.
- # Submit a logic model for both the intervention and comparison group.
- # Describe an ~~A~~Adequate Participatory Planning Process@ which involves C/S/Rs in the preparation of the project, monitoring, provision, and evaluation of services.
- # Demonstrate that the project plan is inclusive; appropriately addresses age, race/ethnic, cultural, language, socio-economics, disability, and gender issues in the proposed design activities, such as models, outreach, intervention, and/or services, and includes appropriate adaptations.
- # Describe adequacy and quality of the intervention models in terms of their conceptual framework, history, setting, cultural and environmental context, program structure, financing, and service array.
- # Describe, where possible, how the intervention model addresses the SAMHSA priority issues of HIV/AIDS.

***Coordinating Center applicant must:***

- # Describe an understanding of the sites= logic model for both the intervention and comparison group.
- # Propose procedures for ensuring study site accountability in project design and implementation.
- # Describe a plan for assisting sites in the development of the standardized cross-site common service intervention.

**Methodology and Evaluation**

***Site applicants must:***

- # Describe calculations of the expected effect size of the service intervention model, and consequently, the needed sample size to achieve adequate statistical power for the pooled data analysis. The recommended sample size for each site is 30 per intervention group and 30 per comparison group.
- # Provide estimates of sample attrition rates and, given those rates, demonstrate the ability to recruit, track and retain the needed sample size in both the intervention and comparison group in order to maintain adequate statistical power for the overall cross-site study at 12-month follow-up.
- # Describe the anticipated number of children in the 5 to 10 year age group eligible for enrollment in this study based on the expected number of women from the ~~AWomen~~ Women, ADM Disorders and Violence Phase II ~~@study~~ study who will consent to have their eligible children enrolled in the Children's Subset Study.
- # Describe appropriateness of the analytic design; strategies to control for bias and confounding variables; and the evaluation of services process, including barriers/pathways to care.
- # Discuss comparability of the proposed study populations across the intervention and comparison groups.
- # Describe and justify sampling/recruitment plans.
- # Describe follow-up plans.
- # State the procedures that will be used to ensure compliance with SAMHSA's need to adhere to GPRA timelines: baseline, six, and 12 month follow-ups. (Note: The GPRA measures do not apply to children ages 5 to 10).

***Coordinating Center applicant must:***

- # Describe plan for assisting sites in the development and refinement of the multi-site protocol.
- # Describe appropriateness of sample size needed from each site for pooled data analysis.

**Measures/Parameters/Indicators**

***Site applicants must:***

- # Clearly state and demonstrate the appropriateness of assessments and instruments that will be utilized to measure the results of the program.

***Coordinating Center applicant must:***

- # Describe how common instruments are going to be identified as being appropriate for the Children's Subset Study.

- # Describe plan for distributing instruments to the study sites.

## **Data Collection, Fidelity, and Analyses**

### ***Site applicants must:***

- # Demonstrate capacity to administer the multi-site protocol, including screening, baseline and follow-up interviews, in accordance with the standards set by the Children's Subcommittee as promulgated by the Steering Committee.
- # Demonstrate the willingness to participate in the cross-site process evaluation conducted by the Coordinating Center including participation in the annual site visit and completion of the Children's Administrative Reporting Form.
- # Implement screening activities and outcome measurements appropriate to the target populations using the multi-site protocol developed in Phase I by the Children's Subcommittee as promulgated by the Steering Committee.
- # Present a plan for collecting data to assess treatment fidelity for both the intervention and comparison groups, citing the appropriate literature and/or instrumentation.
- # Describe the plan to evaluate the processes of implementation and the adherence of interventions and procedures to those proposed.
- # Propose strategies to ensure that data collection occurs in a culturally appropriate and congruent manner.
- # Demonstrate feasibility and capacity for obtaining data from a comparable sample of children in the comparison group.
- # Describe adequacy and appropriateness of strategies for data collection and quality control.
- # Describe plan to obtain the required sample sizes for the multi-site study.
- # Describe plan to incorporate multi-site study measures, including: (1) data collection and data submission plans; (2) implementation of quality control practices; (3) collaboration on data analysis and publication writing; and (4) adherence to Children's Subcommittee as promulgated by the Steering Committee decisions.
- # Describe statistical strategies to provide reliable and valid findings, including analyses to control for bias and confounding variables.
- # Describe plan to ensure C/S/R involvement in the interpretation and dissemination of project findings.
- # Describe the proposed reporting and dissemination plan of the project findings.

### ***Coordinating Center applicant must:***

- # Demonstrate capacity to monitor data collection procedures.
- # Describe plan for analyzing data from the multi-site study.
- # Describe plan for distributing multi-site protocol to the study sites.
- # Describe procedures for conducting annual site visits.

- # Describe the proposed reporting and dissemination plan of the project findings including knowledge products.

**C. Project Management: Implementation Plan, Organization, Staff, Equipment/Facilities, Budget, and Other Support**

***Site applicants must:***

**Implementation Plan**

- # State how the proposed management plan implements the overall design and is timely, feasible, achievable, and realistic, as well as culturally appropriate.
- # Provide an implementation plan time-line in Appendix 1 entitled, Implementation Plan Time-line, that includes tasks, time-lines, and responsible person(s).

***Coordinating Center applicant must:***

- # State how the proposed management plan implements the overall design and is timely, feasible, achievable, and realistic, as well as culturally appropriate.
- # Provide an implementation plan time-line in Appendix 1 entitled, Implementation Plan Time-line, that includes tasks, time-lines, and responsible person(s).

**Organization**

***Site applicants must:***

- # Discuss the capability and experience of the applicant/organization in dealing with similar projects and child populations.
- # Describe the extent to which the organization is collaborating or plans to collaborate with other service agencies, institutes, non-profits, Tribal Councils, National Tribal organizations, universities, clinics, or organizations.
- # Discuss coordination of activities in the Childrens Subset Study with the Women, ADM Disorders and Violence Phase II Study.

***Coordinating Center applicant must:***

- # Discuss the capability and experience of the applicant/organization in dealing with similar projects and child populations.
- # Discuss coordination of activities in the Childrens Subset Study with the Women, ADM Disorders and Violence Phase II Study.

## **Staff**

### ***Site applicants must:***

- # Provide evidence that the proposed staffing is appropriate and adequate for implementation of the project. Separate the staff into two groups: (1) service intervention staff and (2) research/evaluation staff. Describe the qualifications of the project director, study coordinator, evaluator, and other key personnel including proposed consultants and subcontractors.
- # Describe the extent to which the staff is reflective of the target population and demonstrates cultural competence to ensure sensitivity to language, gender, race/ethnicity, physical or cognitive disability, and other cultural factors related to the targeted population.

### ***Coordinating Center applicant must:***

- # Provide evidence that the proposed staffing is appropriate and adequate for implementation of the project. Describe the qualifications of the project director, evaluators, and other key personnel including proposed consultants and subcontractors.

## **Equipment/Facilities**

### ***Site applicants must:***

- # Discuss the availability and adequacy of resources and equipment.
- # Document that the services provided in a location/facility are adequate and accessible and the environment is conducive to the population to be served, as well as to the research and evaluation of the service delivery process.

### ***Coordinating Center applicant must:***

- # Discuss the availability and adequacy of resources and equipment.
- # Document that the facility is adequate for conducting research, evaluation, and technical services.

## **Budget**

### ***Site applicants must:***

- # Provide a detailed, reasonable budget including all identified potential expenses required to achieve successful completion of the project plan and management.
- # If the applicant elects to use funding from this cooperative agreement for service enhancements

- to the Intervention Model, describe the extent to which service enhancement funding conforms to the GFA budget requirements.
- # Describe the degree to which funds from other sources have been leveraged to support services provided on this Subset Study, if applicable.

***Coordinating Center applicant must:***

- # Provide a detailed, reasonable budget including all identified potential expenses required to achieve successful completion of the project plan and management.

**Other Support**

***Site applicants must:***

- # Describe the adequacy of additional resources not budgeted for this GFA that will be utilized to implement this project, if applicable.
- # Describe and discuss the appropriateness of a plan to secure resources in order to phase out or extend this project beyond the federally funded program years, if applicable.

***Coordinating Center applicant must:***

- # Describe the adequacy of additional resources not budgeted for this GFA that will be utilized to implement this project, if applicable.

**Post Award Requirements**

Post award support will be provided to the grantees by SAMHSA staff and through the Coordinating Center to assist grantees in implementing the evaluation, analyzing data, and preparing interim and final reports.

## **Section IV - REVIEW of APPLICATIONS**

**Guidelines**

Applications submitted in response to this GFA will be reviewed for scientific/technical merit in accordance with established PHS/SAMHSA review procedures outlined in the Review Process section of Part II. Applicants must review the Special Considerations/Requirements and Application Procedures sections that follow, as well as the guidance provided in Part II, before completing the application.

**The review criteria A-C below correspond to subsections A-C in Section III above to assist in**

**the application process. Reviewers will respond to each review criterion on the basis of the information provided in Section III by the applicants. Therefore it is important for applicants to follow carefully the outline, headings, and subheadings when providing the requested information.**

Applications will be reviewed and evaluated according to the review criteria that follow. The points noted for each criterion indicate the maximum number of points the reviewers may assign for that criterion if the application is considered to have sufficient merit for scoring. **The bulleted statements that follow each review criterion do not have weights.** The assigned points will be used to calculate a raw score that will be converted to the official priority score.

Peer reviewers will be instructed to review and evaluate each relevant criterion in relation to cultural competence. Points will be deducted from applications that do not adequately address the cultural aspects of the criteria. (See Appendix D in Part II, for guidelines that will be used to assess cultural competence.)

Note: The review criteria applies to site applicants except where noted.

## **Review Criteria**

### **A. Project Description (20 Points)**

#### **Statement of the Problem**

##### ***Site applicant:***

- # Extent to which the problems of children who have mothers with histories of violence and co-occurring disorders are adequately described and understood.
- # Extent to which evidence of the ethnic and cultural variations found in the overall population as well as the proposed study sample is provided.
- # Extent to which the applicant demonstrates the need for service models of care for the proposed sample.
- # Extent to which the applicant provides a description of existing services.
- # Extent to which the applicant describes enhanced services created or implemented as part of this program.
- # Extent to which the literature review demonstrates an understanding of the state-of-the-art and/or science related to the services and treatment of children impacted by family violence or sexual abuse, and/or have been abused or neglected.
- # Extent to which the literature review reflects current state of knowledge regarding culturally competent services in this area and appropriate discussion that demonstrates how the reference citations relate to the design being proposed and the population to be served.

***Coordinating Center Applicant:***

- # Extent to which the literature review demonstrates an understanding of the state-of-the-art and/or science related to the children of women who have histories of violence and co-occurring disorders.

**Target Population**

***Site applicant:***

- # Extent to which the targeted population is clearly defined and appropriate for both the intervention and comparison group.
- # Adequacy of strategies proposed to ensure that the target population (including demographics) is representative of the entire population of children to be served.
- # Extent to which documentation of the sample as children of women who are high end users is provided.
- # If applicable, the extent to which adequate justification for exclusion was demonstrated.

***Coordinating Center Applicant:***

- # Extent to which the applicant demonstrates an understanding of the definition and needs of the target population.

**Purpose and Goals**

***Site applicant:***

- # Extent to which the proposed project purpose adequately addresses the various dimensions of the problem as stated, and is based upon available evidence regarding what might be accomplished.
- # Extent to which the applicant's outline of goals, objectives and timetables demonstrates an understanding of the goals and objectives of the Program as defined in this GFA.
- # Extent to which the outline of goals, objectives and time-tables reflect realistic strategic development in the context of the applicant's current level of service and intervention development.
- # Extent to which the proposed project goal(s) will support the generation of both qualitative and quantitative information and data that are: (a) based on prior evidence and innovation, (b) feasible in terms of issues that are addressed, (c) reflective of C/S/R involvement, and (d) capable of generating appropriate evaluation data.
- # Extent to which the achievement of the goals will advance the field and be assessed as

innovative.

***Coordinating Center Applicant:***

- # Extent to which the applicant demonstrates an understanding of the program goals and objectives.
- # Extent to which the applicant describes how technical assistance will be provided to the study sites so that they can accomplish their goals and objectives.
- # Adequacy of plan for providing logistical and technical support at meetings.

**B. Project Plan (45 Points)**

***Site applicant:***

**Design**

- # Extent to which the applicant describes how the site will implement the standardized cross-site service intervention.
- # Extent to which the Format for Description of Interventions is followed in describing the Trauma-Informed Children's Services and Services as Usual.
- # Extent to which the applicant describes the intervention and comparison group in terms of recruitment strategies, points of entry, eligibility for services, service array, service providers, treatment duration, organizational and staffing plans, level and type of C/S/R involvement, and specific clinical interventions in place.
- # Extent to which an adequate logic model for both the intervention and comparison group is provided.
- # Extent to which the applicant describes an Adequate Participatory Planning Process which involves C/S/Rs in the preparation of the project, monitoring, provision, and evaluation of services.
- # Extent to which the project plan is inclusive; appropriately addresses age, race/ethnic, cultural, language, socio-economics, disability, and gender issues in the proposed design activities, such as models, outreach, intervention, and/or services, and includes appropriate adaptations.
- # Extent to which the adequacy and quality of the intervention models in terms of their conceptual framework, history, setting, cultural and environmental context, program structure, financing, and service array is described.
- # Extent to which, where possible, the applicant shows how the intervention model addresses the SAMHSA priority issues of HIV/AIDS.

***Coordinating Center Applicant:***

- # Extent to which an understanding of the sites= logic model for both the intervention and

- comparison group is described.
- # Extent to which procedures for ensuring study site accountability in project design and implementation is described.
- # Extent to which a description of a plan for assisting sites in the development of the standardized cross-site common service intervention is provided.

## **Methodology and Evaluation**

### ***Site applicant:***

- # Extent to which calculations of the expected effect size of the service intervention model and, consequently, the needed sample size to achieve adequate statistical power for the pooled data analysis is described.
- # Extent to which the applicant provides estimates of sample attrition rates and, given those rates, demonstrates the ability to recruit, track and retain the needed sample size in both the intervention and comparison group in order to maintain adequate statistical power for the overall cross-site study at 12-month follow-up.
- # Extent to which an adequate number of eligible children are available to be enrolled in this study based on the expected number of women from the AWomen, ADM Disorders, and Violence Phase II@study who will give consent for their child=s enrollment.
- # Extent to which the applicant describes appropriateness of the analytic design; strategies to control for bias and confounding variables; and the evaluation of services process, including barriers/pathways to care.
- # Extent to which the applicant describes comparability of the proposed study populations across the intervention and comparison groups.
- # Extent to which a description and justification of sampling/recruitment plans are provided.
- # Extent to which the applicant describes follow-up plans.
- # Extent to which the applicant states the procedures that will be used to ensure compliance with SAMHSA=s need to adhere to GPRA timelines: baseline, six, and 12 month follow-ups.

### ***Coordinating Center Applicant:***

- # Extent to which a description of a plan for assisting sites in the development and refinement of the multi-site protocol is provided.
- # Extent to which the appropriateness of the sample size needed from each site for pooled data analysis is described.

## **Measures/Parameters/Indicators**

### ***Site applicant:***

#      Extent to which the applicant clearly states and demonstrates the appropriateness of assessments and instruments that will be utilized to measure the results of the program.

***Coordinating Center Applicant:***

- # Extent to which the applicant describes how common instruments are going to be identified as being appropriate for the Children's Subset Study.
- # Extent to which a plan for distributing instruments to the study sites is described.

**Data Collection, Fidelity, and Analyses**

***Site applicant:***

- # Extent to which the applicant demonstrates capacity to administer the multi-site protocol, including screening, baseline and follow-up interviews, in accordance with the standards set by the Children's Subcommittee as promulgated by the Steering Committee.
- # Extent to which the applicant demonstrates the capacity and commitment to collect process evaluation data using the Administrative Reporting Form developed in Phase I and participates in the annual site visits by the Coordinating Center.
- # Extent to which the applicant describes the implementation of screening activities and outcome measurements appropriate to the target population using the multi-site protocol developed by the Children's Subcommittee as promulgated by the Steering Committee.
- # Extent to which a plan for collecting data to assess treatment fidelity for both the intervention and comparison groups is described.
- # Appropriateness of plan to evaluate the processes of implementation and the adherence of interventions and procedures to those proposed.
- # Extent to which strategies are proposed to ensure that data collection occurs in a culturally appropriate and congruent manner.
- # Extent to which the applicant demonstrates feasibility and capacity for obtaining data from a comparable sample of children in the comparison group.
- # Adequacy and appropriateness of strategies for data collection and quality control.
- # Adequacy of plan to obtain the required sample sizes for the multi-site study.
- # Adequacy of the plan to incorporate multi-site study measures, including: (1) data collection and data submission plans; (2) implementation of quality control practices; (3) collaboration on data analysis and publication writing; and (4) adherence to Children's Subcommittee through the Steering Committee decisions.
- # Extent to which strategies to draw reliable and valid findings, including analyses to control for bias and confounding variables are described.
- # Extent to which a plan to ensure C/S/R involvement in the interpretation and dissemination of project findings is described.
- # Extent to which the proposed reporting and dissemination plan of the project findings is described.

***Coordinating Center Applicant:***

- # Extent to which the applicant demonstrates capacity to monitor data collection procedures.
- # Extent to which a plan for analyzing data from the multi-site study is described.
- # Extent to which a plan for distributing the multi-site protocol to the study sites is described.
- # Extent to which the procedures for conducting annual site visits are described.
- # Extent to which a description of the proposed reporting and dissemination plan of the project findings including knowledge products is provided.

**C. Project Management: Implementation Plan, Organization, Staff, Equipment/ Facilities, Budget, and Other Support (35 Points)**

**Implementation Plan**

***Site applicant:***

- # Extent to which the proposed management plan implements the overall design and is timely, feasible, achievable, and realistic, as well as culturally appropriate.
- # Extent to which the implementation plan time-line, provided in Appendix 1, includes the appropriate tasks, time-lines and responsible persons.

***Coordinating Center Applicant:***

- # Extent to which the proposed management plan implements the overall design and is timely, feasible, achievable, and realistic, as well as culturally appropriate.
- # Extent to which the implementation plan time-line, provided in Appendix 1, includes tasks, time-lines, and responsible person(s).

**Organization**

***Site applicant:***

- # Capability and experience of the applicant organization with similar projects and child populations.
- # Extent to which there is collaboration with other agencies, institutes, non-profits, Tribal Councils, National Tribal Organizations, universities, clinics, or organizations.
- # Extent to which activities of the Children's Subset Study are coordinated with activities of the Women, ADM Disorders, and Violence Phase II study.

***Coordinating Center Applicant:***

- # Capability and experience of the applicant/organization in dealing with similar projects and child populations.
- # Extent to which activities of the Children's Subset Study are coordinated with activities of the Women, ADM Disorders and Violence Phase II Study.

**Staff**

***Site applicant:***

- # Evidence that the proposed staffing pattern is appropriate and adequate for implementation of this project.
- # Qualifications and experience of the project director, study coordinator, evaluator, and other key personnel, including proposed consultants and subcontractors.
- # Extent to which the staff is reflective of the target population or can demonstrate cultural competence to ensure sensitivity to language, gender, race/ethnicity, physical or cognitive disability, and other cultural factors related to the target population.

***Coordinating Center Applicant:***

- # Evidence that the proposed staffing is appropriate and adequate for implementation of this project.
- # Qualifications and experience of the project director, evaluators, and other key personnel including proposed consultants and subcontractors.

**Equipment/Facilities**

***Site applicant:***

- # Adequacy and availability of resources and equipment.
- # Evidence that the activities or services are provided in locations/facilities that are adequate and accessible, and the environment is conducive to the population to be served.

***Coordinating Center Applicant:***

- # Adequacy and availability of resources and equipment.
- # Evidence that the facility is adequate for conducting research, evaluation, and technical services.

## **Budget**

### ***Site applicant:***

- # Evidence that service enhancement funding conforms to the GFA budget requirements, if applicable.
- # Extent to which funds from other sources have been leveraged to support services provided under this Subset Study, if applicable.

## **Other Support**

### ***Site applicant:***

- # Adequacy of additional resources not budgeted for that will be utilized to implement this project, if applicable.
- # Appropriateness of a plan to secure resources in order to phase out or extend this project beyond the federally funded program years, if applicable.

### ***Coordinating Center Applicant:***

- # Adequacy of additional resources not budgeted for that will be utilized to implement this project, if applicable.

Note: Although the reasonableness and appropriateness of the proposed budget for each year of the proposed project are not review criteria for this GFA, the Initial Review Group will be asked to consider them after the merits of the application have been considered.

## **Section V. SPECIAL CONSIDERATIONS/REQUIREMENTS**

SAMHSA's policies and special considerations/requirements related to this program include:

- # Population Inclusion Requirement
- # Government Performance Monitoring
- # Healthy People 2000 (The Healthy People 2000 priority area(s) related to this program are: alcohol, other drugs, and mental health)
- # Consumer Bill of Rights
- # Promoting Nonuse of Tobacco
- # Supplantation of Existing Funds (put documentation in Appendix 2)
- # Letter of Intent
- # Coordination with Other Federal/Non-Federal Programs (put documentation in Appendix 3)

- # Single State Agency Coordination (put documentation in Appendix 4)
- # Intergovernmental Review (E.O. 12372)
- # Confidentiality/Human Subjects (Each of the three SAMHSA Center Directors has determined that projects funded under this program must meet SAMHSA's Human Subjects requirements).

Specific guidance and requirements for the application related to these policies and special considerations/requirements can be found in Part II in the section by the same name.

## **Section VI - APPLICATION PROCEDURES**

All applicants must use application form PHS 5161-1 (Rev. 6/99), which contains Standard Form 424 (face page). The following must be typed in Item Number 10 on the face page of the application form:

### **TI 00-006 Children's Subset Study**

For more specific information on application guidelines, see the Application Procedures section in Part II. Completed applications must be sent to the following address.

SAMHSA Programs  
Center for Scientific Review  
National Institutes of Health  
Suite 1040  
6701 Rockledge Drive MSC-7710  
Bethesda, MD 20892-7710\*

\*Applicants who wish to use express mail or courier service should change the zip code to 20817

Complete application kits for this program will be provided to all Phase I grantees.

## **APPLICATION RECEIPT AND REVIEW SCHEDULE**

The schedule for receipt and review of applications under this GFA is as follows:

<u>Receipt Date</u>	<u>IRG Review</u>	<u>Council Review</u>	<u>Earliest Start Date</u>
June 13, 2000	July/August 2000	Sept 2000	Sept 2000

Applications must be received by the above receipt date to be accepted for review. An application received after the deadline may be acceptable if it carries a legible proof-of-mailing date assigned by the carrier and the proof-of-mailing date is not later than 1 week prior to the deadline date. Private

metered postmarks are not acceptable as proof of timely mailing. (NOTE: These instructions replace the "Late Applications" instructions found in the PHS 5161-1.)

## **CONSEQUENCES OF LATE SUBMISSION**

Applications received after the above receipt date will not be accepted and will be returned to the applicant without review.

## **APPLICATION REQUIREMENTS/COMPONENT CHECK LIST**

All applicants must use the Public Health Service (PHS) Grant Application form 5161-1 (Rev. 6/99) and follow the requirements and guidelines for developing an application presented in Part I Programmatic Guidance and Part II General Policies and Procedure Applicable to all SAMHSA Applications for Discretionary Grants and Cooperative Agreements..

The application should provide a comprehensive framework and description of all aspects of the proposed project. It should be written in a manner that is self-explanatory to reviewers unfamiliar with the prior related activities of the applicant. It should be succinct and well organized, should use section labels that match those provided in the table of contents for the Program Narrative that follows, and must contain all the information necessary for reviewers to understand the proposed project.

To ensure that sufficient information is included for the technical merit review of the application, the Programmatic Narrative section of application must address, but is not limited to, issues raised in the sections of this document entitled:

1. Program Description
2. Project Requirements
3. Review of Applications

Note: It is requested that on a separate sheet of paper, the name, title, and organization affiliation of the individual who is primarily responsible for writing the application be provided. Providing this information is voluntary and will in no way be used to influence the acceptance or review of the application. When submitting the information, please insert the completed sheet behind the application face page.

A **COMPLETE** application consists of the following components **IN THE ORDER SPECIFIED BELOW**. A description of each of these components can be found in Part II.

\_\_\_FACE PAGE FOR THE PHS 5161-1 (Standard Form 424 - See Appendix A in Part II for instructions.)

\_\_\_OPTIONAL INFORMATION ON APPLICATION WRITERS (See note above).

\_\_\_ABSTRACT (not to exceed 35 lines)

\_\_\_TABLE OF CONTENTS (include page numbers for each of the major sections of the Program Narrative, as well as for each appendix)

\_\_\_BUDGET FORM (Standard Form 424A - See Appendix B in Part II for instructions.)

\_\_\_PROGRAM NARRATIVE (The information requested for sections A-C of the Program Narrative is discussed in the subsections with the same titles in Section III - Project Requirements, and Section IV - Review of Applications. **Sections A-C may not exceed 25 single-spaced pages. Applications exceeding these page limits will not be accepted for review and will be returned to the applicant.**

- \_\_\_A. Project Description: Statement of the Problem, Target Population, Purpose and Goals
- \_\_\_B. Project Plan: Design, Methodology and Evaluation, Measures/Parameters/ Indicators, Data Collection, Fidelity, and Analyses
- \_\_\_C. Project Management: Implementation Plan, Organization, Staff, Equipment/Facilities, Budget, and Other Support

**There are no page limits for the following sections D-G except as noted in F. Biographical Sketches/Job Descriptions. Sections D-G will not be counted toward the 25 page limitation for sections A-C.**

- \_\_\_D. Literature Citations (This section must contain complete citations, including titles and all authors, for literature cited in the application.)
- \_\_\_E. Budget Justification/Existing Resources/Other Support

\_\_\_Sections B, C, and E of the Standard Form 424A must be filled out according to the instructions. A line item budget and specific justification in narrative form for the first project year's direct costs AND for each future year must be provided. For contractual costs, provide a similar yearly breakdown and justification for ALL costs (including overhead or indirect costs).

\_\_\_All other resources needed to accomplish the project for the life of the grant (e.g., staff, funds, equipment, office space) and evidence that the project will have access to these, either through the grant or, as appropriate, through other resources, must be specified.

Other Support @Other Support@ refers to all current or pending support related to this application. Applicant organizations are reminded of the necessity to provide full and reliable information regarding "other support," i.e., all Federal and non-Federal active or

pending support. Applicants should be cognizant that serious consequences could result if failure to provide complete and accurate information is construed as misleading to the PHS and could, therefore, lead to delay in the processing of the application. In signing the face page of the application, the authorized representative of the applicant organization certifies that the application information is accurate and complete.

For your organization and key organizations that are collaborating with you in this proposed project, list all currently active support and any applications/proposals pending review or funding that relate to the project. If there are none, state "none." For all active and pending support listed, also provide the following information:

1. Source of support (including identifying number and title).
2. Dates of entire project period.
3. Annual direct costs supported/requested.
4. Brief description of the project.
5. Whether project overlaps, duplicates, or is being supplemented by the present application; delineate and justify the nature and extent of any programmatic and/or budgetary overlaps.

     F. Biographical Sketches/Job Descriptions

A biographical sketch must be included for the project director and for other key positions. Each of the biographical sketches must not exceed **2 pages** in length. In the event that a biographical sketch is included for an individual not yet hired, a letter of commitment from that person must be included with his/her biographical sketch. Job descriptions for key personnel must not exceed **1 page** in length. The suggested contents for biographical sketches and job descriptions are listed in Item 6 in the Program Narrative section of the PHS 5161-1.

     G. Confidentiality/Protection of Human Subjects

The information provided in this section will be used to determine whether the level of protection of human subjects appears adequate or whether further provisions are needed, according to standards set forth in Title 45, Part 46, of the Code of Federal Regulations. Adequate protection of human subjects is an essential part of an application and will be considered in funding decisions.

Projects proposed under this announcement may expose participants to risks in as many ways as projects can differ from each other. Following are some examples, but they do not exhaust the possibilities. Applicants should report in this section any foreseeable risks for project participants, and the procedures developed to protect participants from those risks, as set forth below. Applicants should discuss how each element will be addressed, or why it does not apply to the project.

Note: So that the adequacy of plans to address protection of human subjects, confidentiality, and other ethical concerns can be evaluated, the information requested below, which may appear in other sections of the narrative, should be included in this section of the application as well.

1. Protection from Potential Risks:

- (a) Identify and describe any foreseeable physical, medical, psychological, social, legal, or other risks or adverse effects, besides the confidentiality issues addressed below, which are due either to participation in the project itself, or to the evaluation activities.
- (b) Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects and the rationale for their nonuse.
- (c) Describe the procedures that will be followed to minimize or protect participants against potential risks, including risks to confidentiality.
- (d) Where appropriate, specify plans to provide needed professional intervention in the event of adverse effects to participants.

2. Equitable selection of participants:

Target population(s):

Describe the sociodemographic characteristics of the target population(s) for the proposed project, including age, gender, racial/ethnic composition, and other distinguishing characteristics (e.g., homeless youth, foster children, children of substance abusers, pregnant women, institutionalized individuals, or other special population groups).

Recruitment and Selection:

- (a) Specify the criteria for inclusion or exclusion of participants and explain the rationale for these criteria.
- (b) Explain the rationale for the use of special classes of subjects, such as pregnant women, children, institutionalized mentally disabled, prisoners, or others who are likely to be vulnerable.
- (c) Summarize the recruitment and selection procedures, including the circumstances under which participation will be sought and who will seek it.

3. Absence of Coercion:

(a) Explain whether participation in the project is voluntary or mandatory. Identify any potentially coercive elements that may be present (e.g., court orders mandating individuals to participate in a particular intervention or treatment program).

(b) If participants are paid or awarded gifts for involvement, explain the remuneration process.

(c) Clarify how it will be explained to volunteer participants that their involvement in the study is not related to services and the remuneration will be given even if they do not complete the study.

4. Appropriate Data Collection:

(a) Identify from whom data will be collected (e.g., participants themselves, family members, teachers, others) and by what means or sources (e.g., school records, personal interviews, written questionnaires, psychological assessment instruments, observation).

(b) Identify the form of specimens (e.g., urine, blood), records, or data. Indicate whether the material or data will be obtained specifically for evaluative/research purposes or whether use will be made of existing specimens, records, or data. Also, where appropriate, describe the provisions for monitoring the data to ensure the safety of subjects.

(c) Provide, in Appendix No. 5, entitled "Data Collection Instruments/Interview Protocols," copies of all available data collection instruments and interview protocols that will be used or proposed to be used in the case of cooperative agreements.

5. Privacy and Confidentiality:

Specify the procedures that will be implemented to ensure privacy and confidentiality, including by whom and how data will be collected, procedures for administration of data collection instruments, where data will be stored, who will/will not have access to information, and how the identity of participants will be safeguarded (e.g., through the use of a coding system on data records; limiting access to records; storing identifiers separately from data).

Note: If applicable, grantees must agree to maintain the confidentiality of alcohol and

drug abuse client records in accordance with the provisions of Title 42 of the Code of Federal Regulations, Part 2 (42 CFR, Part 2).

6. Adequate Consent Procedures:

(a) Specify what information will be provided to participants regarding the nature and purpose of their participation; the voluntary nature of their participation; their right to withdraw from the project at any time, without prejudice; anticipated use of data; procedures for maintaining confidentiality of the data; potential risks; and procedures that will be implemented to protect participants against these risks.

(b) Explain how consent will be appropriately secured for youth, elderly, low literacy and/or for those who English is not their first language.

Note: If the project poses potential physical, medical, psychological, legal, social, or other risks, awardees may be required to obtain written informed consent.

(c) Indicate whether it is planned to obtain informed consent from participants and/or their parents or legal guardians, and describe the method of documenting consent. For example: Are consent forms read to individuals? Are prospective participants questioned to ensure they understand the forms? Are they given copies of what they sign?

Copies of sample (blank) consent forms should be included in Appendix No. 6, entitled "Sample Consent Forms." If appropriate, provide English translations.

Note: In obtaining consent, no wording should be used that implies that the participant waives or appears to waive any legal rights, is not free to terminate involvement with the project, or releases the institution or its agents from liability for negligence.

(d) Indicate whether separate consents will be obtained for different stages or aspects of the project, and whether consent for the collection of evaluative data will be required for participation in the project itself. For example, will separate consent be obtained for the collection of evaluation data in addition to the consent obtained for participation in the intervention, treatment, or services project itself? Will individuals not consenting to the collection of individually identifiable data for evaluative purposes be permitted to participate in the project?

7. Risk/Benefit Discussion:

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be

expected to result.

\_\_\_ APPENDICES (Only the appendices specified below may be included in the application. **These appendices must not be used to extend or replace any of the required sections of the Program Narrative.** The total number of pages in the appendices **CANNOT EXCEED 30 PAGES**, excluding all instruments.)

- \_\_\_ Appendix 1: Implementation Plan Time-line
- \_\_\_ Appendix 2: Non-Supplantation of Funds Documentation
- \_\_\_ Appendix 3: Letters of Coordination/Support
- \_\_\_ Appendix 4: Copy of Letter(s) to SSA(s)
- \_\_\_ Appendix 5: Data Collection Instruments/Interview Protocols
- \_\_\_ Appendix 6: Sample Consent Forms

\_\_\_ ASSURANCES NON-CONSTRUCTION PROGRAMS (STANDARD FORM 424B)

\_\_\_ CERTIFICATIONS

\_\_\_ DISCLOSURE OF LOBBYING ACTIVITIES

\_\_\_ CHECKLIST PAGE (See Appendix C in Part II for instructions)

## **TERMS AND CONDITIONS OF SUPPORT**

For specific guidelines on terms and conditions of support, allowable items of expenditure and alterations and renovations, applicants must refer to the sections in Part II by the same names.

### Reporting Requirements

For the SAMHSA policy and requirements related to reporting, applicants must refer to the Reporting Requirements section in Part II.

### Lobbying Prohibitions

SAMHSA's policy on lobbying prohibitions is applicable to this program; therefore, applicants must refer to the section in Part II by the same name.

## **AWARD DECISION CRITERIA**

Applications will be considered for funding on the basis of their overall technical merit as determined through the IRG and the CSAT, CSAP, and CMHS National Advisory Councils review process.

Other award criteria will include:

# Availability of funds.

## CONTACTS FOR ADDITIONAL INFORMATION

Questions concerning program issues may be directed to:

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5600 Fishers Lane  
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Questions regarding grants management issues may be directed to:

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## APPENDIX A. BIBLIOGRAPHY

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## **APPENDIX B**

### **FORMAT FOR DESCRIPTION OF INTERVENTIONS**

#### **Trauma-Informed Children=s Services (Intervention Site)**

##### **Experimental Intervention**

- I. Goals of the Intervention
- II. Strategies to Achieve Goals
  - A. Service Model
    - # Description of service model
    - # Specific sequence of intervention components (e.g., screening, assessment, assignment).
    - # Services
      - For each service provide:
        - # Description/content
        - # Number of hours per week
        - # Expected duration
        - # Location(s)
        - # Staffing
    - # Clinical/Individual Level Services Trauma-Informed Strategies
      - For each strategy describe:
        - # Specific activities included in strategy.
        - # Organizations and staff involved - by whom?
        - # Timing of these activities - when?
        - # How trauma-informed will be accomplished?
    - # C/S/R Involvement Strategies
      - For each strategy describe:
        - # Specific activities included in strategy
        - # Timing of these activities - when?

##### **Existing Services**

- I. Description of Services Currently Available
  - A. Services
    - For each service provide:
      - # Description/content
      - # Number of hours per week
      - # Expected duration
      - # Location(s)
      - # Staffing

## II. Characteristics of Services Currently Available

Describe the services currently available with respect to:

- # Range of core services
- # Clinical/individual level
- # Involvement of C/S/Rs
- #

Those that are trauma-informed

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## **Services as Usual (Comparison Site)**

### I. Description of Services Currently Available

#### A. Services

For each service provide:

- # Description/content
- # Number of hours per week
- # Expected duration
- # Location(s)
- # Staffing

### II. Characteristics of Services Currently Available

Describe the services currently available with respect to:

- # Range of core services
- # Clinical/individual level
- # Involvement of C/S/Rs
- # Those that are trauma-informed

Note: Services as usual are expected to be less trauma-informed, less integrated, less comprehensive, and have a lower involvement of C/S/Rs than the trauma-informed services.